

Manufacturer's **Declaration of Conformity**

Document Id:	PD-531601 Rev:04	
State:	Released	
Created by:	Zahrah Chaudhary	
Title:	Primary surgical gowns, sterile	
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We, Mölnlycke Health Care AB, Gamlestadsvägen 3C, Box 13080, SE-402 52 Göteborg, Sweden being exclusively responsible manufacturer for conformity of the device/s; declare that the devices listed in the attached schedule are in conformity with the provisions of the Council Directive 93/42/EEC of 14 June 1993, as amended by 2007/47/EEC, concerning medical devices, the Medical Devices Act SFS 1993:584 and the Swedish Medical Product Agency regulations and guidelines: Medical Devices, LVFS 2003:11 as amended by LVFS 2009:18.

Trade name / Product name:	Primary Surgical Gowns
Product Classification:	MDD Class IS
Sterility:	Sterile
Measuring Function:	No

This declaration is supported by a conformity assessment procedure in accordance with Annex/ es: V, VII

Certificate number:	CE 01966			
Issued by:	BSi	ld No:		
	(Notified Body Name)		(Notified Body)	
NB. For non-sterile, non-measuring class I products there is no Notified Body certificate				

Mölnlycke Health Care issues this declaration in recognition of all applicable harmonised standards.

Signed for and on behalf of Mölnlycke Health Care

Date: 2021-06-22 Function:

Regulatory Affairs Excellence Manager

Karin Darle Olsson Name: Signature: hanie Dule aun



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Product Reference:	Product Descriptor:	GMDN Code:
98000622	SURGICAL GOWN	35091 Operating room gown, single- use
98000623	SURGICAL GOWN	35091 Operating room gown, single- use
98000624	SURGICAL GOWN	35091 Operating room gown, single- use
98000625	SURGICAL GOWN	35091 Operating room gown, single- use
98000722	SURGICAL GOWN	35091 Operating room gown, single- use
98000723	SURGICAL GOWN	35091 Operating room gown, single- use
98000724	SURGICAL GOWN	35091 Operating room gown, single- use
98000725	SURGICAL GOWN	35091 Operating room gown, single- use